

**REMARKS**

Claims 1, 2, 4, 6, 13 and 14 are pending in the above-identified application. Support for the changes to claim 1 is found, for example, at page 19, lines 17-22 of the present specification. Support for new claims 13 is found at page 19, lines 17-22. Support for new claim 14 is found in Example 5 at pages 29-30 of the present specification.

**Removal of Issues under 35 USC 112**

Claims 1, 2, 4 and 6 have been rejected under 35 USC 112, second paragraph, as being indefinite with respect to the clarity of the contents of the absorption aid recited in claim 1. Claim 1 has been amended so as to remove this clarity issue, such that this rejection should be withdrawn.

**Issues under 35 USC 103(a)**

Claims 1, 4 and 6 have been rejected under 35 USC 103(a) as being unpatentable over Nishino '189 (JP 07-171189) and further in view of Tanaka '339 (WO 99/24043 corresponding to US 6,689,339).

Claim 2 has been rejected under 35 USC 103(a) as being unpatentable over Nishino '189 in view of Tanaka '339, and further in view of Westwood '340 (WO 98/173340).

The above rejections are traversed based on the following reasons.

**Present Invention and Its Advantages**

The present invention is directed to a carbon dioxide external administration device which includes a sealing enclosure member containing an absorption aid together with a gas supply for supplying carbon dioxide gas into the sealing enclosure member, wherein the absorption aid is a viscous material containing sodium alginate or propylene glycol alginate, as recited in claim 1, for example. The device of the present invention advantageously provides for the dissolution of carbon dioxide in the absorption aid so as to allow for advantageously effective transdermal or transmucosal absorption of the carbon dioxide into the skin tissue. The

effectiveness of the device of the present invention is supported by the numerous examples described at pages 23-37 of the present specification.

In order to further support the advantageous properties exhibited by the present invention over an example from the prior art, believed by Applicant to be the closest prior art example, Applicant hereby submits the Declaration of Masaya Tanaka under 37 CFR 1.132 (herein the "Tanaka Declaration"). The Tanaka Declaration compares Example 2 described at pages 25-26 of the present specification against Example 299 of Tanaka '339. As noted above and as described at the present specification, the device of the present invention advantageously provides for the dissolving carbon dioxide in order to enhance transdermal and/or transmucosal absorption thereof. In contrast, as discussed in more detail below, Tanaka '339 discloses aqueous viscous compositions and methods employing the same wherein the compositions are required to retain carbon dioxide bubbles so that the carbon dioxide gas from the bubbles is exposed to the skin tissue directly, rather than being administrated while dissolved in a solution as in the present invention. The Tanaka Declaration shows that Example 2 of the present invention exhibits advantageously higher skin temperature properties when compared to Example '299 of Tanaka '339. As noted in section (4) on pages 3-4 of the Tanaka Declaration, an increase in skin temperature correlates to an increase in skin moisture content and sebum output which is consistent with Example 1 at pages 23-25 of the present specification. The Tanaka Declaration concludes that Example 2 in accordance with the present invention and employing sodium alginate, as also used in Example 299 of Tanaka '339, exhibited advantageously improved skin temperatures which correlates to improved skin moisture content and sebum output properties. In this regard, note that the color versions of the gloved hands shown in Table 2 correspond to an advantageously strong shade of green for Subjects A and B of Example 2, as compared to a disadvantageously strong shade of blue for Subjects A and B of Example 299 of Tanaka '339. Finally, the Tanaka Declaration explains that the results shown for the use of sodium alginate are expected to correspond to results expected for replacing this component with propylene glycol alginate, a compound to having similar properties in the context of its use here.

*Distinctions over Cited References*

Tanaka '339 discloses viscose compositions which contain carbon dioxide in gaseous or "bubble" form as mentions, for example, at column 2, lines 37-41 and column 6, lines 25-33, among other portions of the description. Tanaka '339 repeatedly makes it very clear that the carbon dioxide gas is to remain in the form of bubbles for exposure to the skin tissue.

Tanaka '339 fails to disclose a device having an absorption aid that is a viscous material containing sodium alginate or propylene glycol alginate which dissolves carbon dioxide gas, such that the carbon dioxide is no longer in gaseous or "bubble" form. The Tanaka Declaration discussed above clearly evidences the fact that the dissolved carbon dioxide employed in the absorption aid of the present invention exhibits advantageously improved skin temperature raising properties which ultimately correspond to improved transdermal and/or transmucosal absorption of the carbon dioxide, in contrast to the closest example disclosed by Tanaka '339, i.e. Example 299, which is comparatively inferior in this regard. Note that Example 299 of Tanaka '339 includes sodium bicarbonate which may account for the preservation of carbon dioxide in its gaseous state, since a carbonate can be used to generate carbon dioxide under appropriate conditions as described in Tanaka '339. In any case Tanaka '339 fails to disclose or suggest the present invention. Further, even assuming that Tanaka '339 supports an allegation of *prima facie* obviousness, such obviousness has been rebutted by the evidence of unexpected, advantageous properties shown in the Tanaka Declaration discussed above. Therefore, the above rejections based on Tanaka '339 should be withdrawn.

Nishino '189 and Westwood '340 both fail to make up for the above-noted deficiencies of Tanaka '339. Nishino '189 and Westwood '340 are directed to devices which provide a seal for a gas, such as carbon dioxide gas, when it is being exposed to the skin or a limb. However, both of these references fall far short of disclosing, suggesting or providing any basis for one skilled in the art to employ an absorption aid for dissolving carbon dioxide gas, as employed in the device of the present invention. Thus, significant patentable distinctions exist over both of these references, whether taken separately or combined with Tanaka '339. Therefore, the above rejections based on these references in combination with Tanaka '339 should be withdrawn.

If any questions arise in the above matters, please contact Applicant's representative, Andrew D. Meikle (Reg. No. 32,868), in the Washington Metropolitan Area at the phone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: February 2, 2010

Respectfully submitted,

By   
Andrew D. Meikle  
Registration No.: 32,868  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 Gatehouse Road  
Suite 100 East  
P.O. Box 747  
Falls Church, Virginia 22040-0747  
(703) 205-8000  
Attorney for Applicant

Enclosures: Tanaka Declaration under 37 CFR 1.132